UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
THIS DOCUMENT RELATES TO: *State of Montana v. Abbott Labs, Inc., et al.*, 02-CV-12084-PBS; *State of Nevada v. American Home Products Corp., et al.*, 02-CV-12086-PBS	Civil Action No. 01-CV-12257-PBS Judge Patti B. Saris

DEFENDANTS' MOTION TO DISMISS THE STATE OF MONTANA'S SECOND AMENDED COMPLAINT AND THE STATE OF NEVADA'S AMENDED COMPLAINT

Pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6), the undersigned Defendants respectfully move this Court jointly for dismissal of all claims against them in the State of Montana's Second Amended Complaint and the State of Nevada's Amended Complaint. The grounds for this motion are stated in: (1) the Consolidated Memorandum in Support of Defendants' Motion to Dismiss, in which nearly all defendants join; and (2) the individual memoranda of law filed by some defendants, which they have submitted to address issues specific to them or issues that were not included in the Consolidated Memorandum. This Motion is submitted on behalf of all defendants who have been properly served.

WHEREFORE, for the reasons set forth in the memoranda described above, the Defendants respectfully request that the Court grant their motion to dismiss the claims against them in the State of Montana's Second Amended Complaint and the State of Nevada's Amended Complaint and enter an Order:

a. dismissing all claims in the aforementioned Complaints with prejudice; and

b. providing such other and further relief as the Court deems just and proper.

Respectfully submitted,

ON BEHALF OF LISTED DEFENDANTS IN THE ABOVE-CAPTIONED ACTIONS,

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DATE: September 15, 2003

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ON BEHALF OF:

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AMGEN, INC.

APOTHECON, INC.

ASTRAZENECA PHARMACEUTICALS LP

AVENTIS BEHRING L.L.C.

AVENTIS PHARMACEUTICALS, INC.

B. BRAUN OF AMERICA

BAXTER HEALTHCARE CORPORATION

BAXTER INTERNATIONAL, INC.

BAYER CORPORATION

BEDFORD LABORATORIES

BEN VENUE LABORATORIES, INC.

BOEHRINGER INGLEHEIM CORP.

BRISTOL-MYERS SQUIBB CO.

CENTOCOR, INC.

DEY, INC.

GENSIA, INC.

GENSIA SICOR PHARMACEUTICALS, INC.

HOECHST MARION ROUSSEL, INC.

IMMUNEX CORP.

JANSSEN PHARMACEUTICAL PRODUCTS, L.P.

JOHNSON & JOHNSON

MCNEIL-PPC, INC.

NOVARTIS PHARMACEUTICALS CORPORATION

ONCOLOGY THERAPEUTICS NETWORK CORPORATION

ORTHO BIOTECH

PFIZER, INC.

PHARMACIA CORPORATION

PHARMACIA & UPJOHN, INC.

SCHERING-PLOUGH CORPORATION

SMITHKLINE BEECHAM CORPORATION

TAP PHARMACEUTICAL PRODUCTS, INC.

WARRICK PHARMACEUTICALS CORPORATION

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *State of Montana v. Abbott Labs, Inc., et al.*, 02-CV-12084-PBS *State of Nevada v. American Home Products Corp., et al.*,02-CV-12086-PBS	

CONSOLIDATED MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE STATE OF MONTANA'S SECOND AMENDED COMPLAINT AND THE STATE OF NEVADA'S AMENDED COMPLAINT

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MISCELLANEOUS

The States of Montana and Nevada assert three distinct kinds of claims under Montana and Nevada law: (1) the now-familiar AWP claims brought on behalf of Medicare beneficiaries and private health plans (the States assert these claims in a *parens patriae* representative capacity); (2) a new class of AWP claims brought on behalf of the States seeking recovery of state Medicaid funds based on Nevada's and Montana's decision to utilize an AWP-based system of reimbursement; and (3) "Best Price" claims brought on behalf of the States for alleged violations of the federal Medicaid rebate contract between each defendant and HHS. These claims fail for several reasons.

First, the Best Price claims, all of which are premised on state law, are preempted by the federal Medicaid Rebate Statute, which (1) defines the term "best price"; (2) requires a uniform Rebate Agreement between HHS and each manufacturer; and (3) vests compliance and enforcement authority exclusively with HHS and the federal government. This carefully-designed statutory and regulatory system would be seriously undermined if each State was permitted, through litigation, to define key statutory terms such as "best price" and establish the obligations of the Rebate Agreement to which the States are not even parties. *See Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 347-53 (2001). *Second*, the States' AWP claims and Best Price claims (if not preempted by federal law) fail because they do not satisfy the elements of the various state statutes asserted by Montana and Nevada. *Third*, plaintiffs' claims fail to satisfy Rule 9(b). Nevada and Montana fail to identify even one allegedly false "best price" report involving a single manufacturer or drug, and the conclusory allegations regarding non-Medicare drugs and pharmacy benefit managers ("PBMs") are virtually identical to those previously dismissed by the Court.[1]

[1] This Consolidated Memorandum is submitted jointly on behalf of all defendants who have been properly served.

STATEMENT OF THE CASE

A. Summary of the Montana and Nevada Allegations.

The AWP claims, brought on behalf of the States and their residents, closely track the MDL Amended Master Consolidated Class Action Complaint ("AMCC"), which is subject to a pending motion to dismiss. Both States seek to recover on behalf of three discrete AWP classes, the first two in a *parens patriae* capacity: (1) Medicare beneficiaries residing in Montana and Nevada; (2) unidentified "third-party payors" that pay for drugs, including thousands of drugs obtained outside the Medicare and Medicaid frameworks, through private contracts with PBMs; and (3) the States themselves, for allegedly excessive payments to providers under each State's Medicaid program. *See* Mont. Cplt. ¶¶ 166, 201-09; Nev. Cplt. ¶¶ 129, 164-72. The payments by the States are at issue because Montana and Nevada decided to reimburse most Medicaid providers for prescription drugs at rates pegged to AWP -- Montana reimburses at AWP-15%, *see* Mont. Cplt. ¶ 162 (*citing* Mont. Admin. R. 37.86.1101), and Nevada reimburses at AWP-10% plus a $4.76 dispensing fee. *See* Nev. Cplt. ¶ 126 (*citing Nevada Medicaid Servs. Manual* § 1204.2).

Second, in the space of a few paragraphs (*see* Mont. Cplt. ¶¶ 612-23; Nev. Cplt. ¶¶ 392-403), the States conclusorily allege on their own behalf that the "Defendants" inflate the "best prices" of various unnamed drugs in violation of the Medicaid Rebate Statute and each defendant's individual Rebate Agreements with HHS. Without identifying a single Best Price report or particular Best Price to which they object, the States conclusorily allege that "Defendants" collectively failed "to include" in the Best Prices reported to HHS various unnamed "free goods," "discounts," "rebates," and "educational grants and other programs." Mont. Cplt. ¶ 612; Nev. Cplt. ¶ 392. Because the Best Price calculations to HHS were incorrect,

the States allege, the Montana and Nevada Medicaid programs are deprived of the "full rebates" due under the federal Medicaid program. Mont. & Nev. Cplts. ¶ 12.

B. Montana's and Nevada's Decision to Reimburse Providers Based on AWP.

Unlike the Medicare program, which is required by Congress to reimburse for eligible prescription drugs on the basis of AWP, the federal Medicaid program provides the States with some flexibility to establish their own prescription drug reimbursement systems. *See* Mont. Cplt. ¶ 159; Nev. Cplt. ¶ 124. In general, federal regulations limit Medicaid reimbursement for prescription drugs to the lesser of the provider's "usual and customary charges," or "[e]stimated acquisition costs ["EAC"] plus reasonable dispensing fees established by the [state Medicaid] agency." 42 C.F.R. §§ 447.331(b)(1)-(b)(2). EAC is defined as the state Medicaid agency's "best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." 42 C.F.R. § 447.301. These regulations give state Medicaid programs latitude in determining EAC. Exercising their discretion, several States do not reimburse based on AWP, but upon "wholesale acquisition cost," acquisition cost, or some other benchmark.[2] Montana and Nevada, on the other hand, use discounted AWP for most drugs in their determination of EAC -- Montana reimburses at AWP-15%, and Nevada reimburses at AWP-10% plus a $4.76 dispensing fee. *See* Mont. Cplt. ¶ 162; Nev. Cplt. ¶ 126.[3]

As set forth in greater detail below, Montana and Nevada have known for ***decades*** that the published AWPs often exceed provider acquisition costs. *See infra* pages 13-16. More

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[2] *See, e.g.*, Ala. Admin. Code R. 560-X-16.06 (2002) (WAC + 9.2%); Mass. Regs. Code tit. 114.3 § 31.01 (2003) (WAC + 10%); 1 Tex. Admin. Code § 355.8541 (2003) ("wholesale estimated acquisition cost," or "direct estimated acquisition cost," or "maximum allowable cost" for multiple-source drugs).

[3] Montana also reimburses at "maximum allowable cost" with respect to all formulations of a multiple-source drug with three or more suppliers. *See* Mont. Cplt. ¶ 188.

significantly, the States -- and Montana in particular -- were repeatedly informed by HHS that using AWP as a benchmark would reimburse pharmacies at rates much higher than their acquisition costs. *Id.*

C. The Medicaid Rebate Program.

In 1990, concerned that state Medicaid programs were over-paying for prescription drugs to physicians and pharmacies, Congress established the Medicaid rebate program to require that participating drug manufacturers offer the States additional discounts on prescription drugs. *See* 42 U.S.C. § 1396r-8 *et seq.* (the "Rebate Statute"). Unlike other aspects of the federal Medicaid program, in which States are given discretion to establish state Medicaid plans and procedures (such as a prescription drug reimbursement formula based on AWP), the rebate program contains a uniform set of definitions and is based on a uniform contract between each manufacturer and HHS. First, the Rebate Statute requires participating manufacturers to enter into a uniform Rebate Agreement with the Secretary of HHS. *See* 42 U.S.C. § 1396r-8(a)(1); Mont. Cplt. ¶ 603; Nev. Cplt. ¶ 383; *see also* 56 Fed. Reg. 7049 (Feb. 21, 1991) (model HHS Rebate Agreement) (Ex. 1). The Rebate Agreement, together with the Rebate Statute, establishes the obligations of a manufacturer to pay rebates to the States. States are *not* parties to the Rebate Agreement, which is "governed by federal common law." *See* Rebate Agreement at § IX(e) (Ex. 1); *State of Montana v. Abbott Labs, et al.*, 266 F. Supp.2d 250 259 (D. Mass. 2003).

Second, the Rebate Agreement and the Rebate Statute establish the calculation and process for submitting the best price reports. *See* Mont. Cplt. ¶ 604; Nev. Cplt. ¶ 384. This federally-created calculation provides for quarterly rebates for most "covered outpatient drugs" (*id.*) as follows: (1) the total number of units of each dosage form and strength paid for under the state plan in the rebate period; multiplied by (2) the greater of (a) the difference between the "Average Manufacturer Price" ("AMP") and the "best price," or (b) a minimum rebate

percentage equal to 15.1% for single-source and innovator multiple-source drugs. *See* 42 U.S.C. § 1396r-8(c)(1)(B)(i); *see also* Mont. Cplt. ¶ 608; Nev. Cplt. ¶ 388. The terms "AMP" and "best price" are defined in the Rebate Statute and the Rebate Agreement. 42 U.S.C. §§ 1396r-8(c)(1)(C)(i)-(ii) & (k)(1); Ex. 1 at §§ I(a), I(d).

Third, the Rebate Statute and the Rebate Agreement require drug manufacturers to report AMP and best price to the Secretary of HHS -- ***not*** to the States -- on a quarterly basis. *See* 42 U.S.C. § 1396r-8(b)(3)(A); Ex. 1 at § II(e). The Secretary does not provide this confidential best price data to the States, but instead gives them the "Unit Rebate Amount" for each covered drug and dosage. *See* 42 U.S.C. § 1396r-8(b)(2)(A); Ex. 1 at §§ I(n), (dd). States, in turn, provide manufacturers with "Medicaid Utilization Information," or the total number of units of each dosage form and strength of each covered outpatient drug.

Finally, the Rebate Statute and the Rebate Agreement provide for exclusively federal enforcement of the rebate program. The Secretary -- ***not*** the States -- is empowered to "survey" manufacturers that "directly distribute their covered outpatient drugs to verify manufacturer prices" (42 U.S.C. § 1320a-7c) and may "impose civil monetary penalties" up to "$100,000 for each item" if a manufacturer "refuses a request for information about charges or prices . . . in connection with a survey" or "knowingly provides false information." Ex. 1 at §§ III(b), IV(a); *see also* 42 U.S.C. § 1396r-8(b)(3)(B). The Secretary also is empowered to impose additional monetary penalties "for failure to provide timely information on AMP [or] Best Price" at a rate of $10,000 "for each day in which such information has not been provided." Ex. 1 at § IV(c).

The Secretary has additional authority to direct state Medicaid agencies to debar non-complying manufacturers. *See* 42 U.S.C. § 1320a-7a.[4]

ARGUMENT

I. THE BEST PRICE CLAIMS SHOULD BE DISMISSED.

The States conclusorily allege that "defendants" improperly inflate the "best prices" of various unnamed drugs, in violation of the Rebate Statute and each manufacturer's obligations under the Rebate Agreement with HHS. This asserted failure to comply with each manufacturer's obligation to the federal government is alleged to violate the Montana and Nevada "deceptive trade practice" statutes (Mont. Count II; Nev. Count III), the Montana and Nevada "Medicaid fraud" statutes (Mont. Count III; Nev. Count V), and the Montana "False Claims" act (Mont. Count IV). These Best Price claims fail for two reasons. First, they are preempted by the Medicaid Rebate Statute, which together with the Rebate Agreement establishes each defendant's obligations to report best price. Second, even if not preempted, these claims fail because they do not (and cannot) allege violations of the Montana and Nevada statutes.

A. The Best Price Claims Alleged Under Montana and Nevada Law Are Preempted by the Medicaid Rebate Statute.

The Supremacy Clause of the United States Constitution (Art. VI, cl. 2), "invalidates state laws that interfere with, or are contrary to, federal law." *Hillsborough Cty., Fla. v.*

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[4] CMS has also made clear through a series of directives to all state Medicaid Directors that CMS -- ***not*** the States -- has ultimate authority to address failures by manufacturers to fulfill their obligations under the Rebate Agreement. Program Release 55, for example, instructs States that in the event of a manufacturer's refusal to pay rebates, the State should contact the regional CMS drug rebate coordinator for enforcement action or dispute resolution. *See HCFA/CMS Medicaid Drug Rebate Program Release No. 55* at 2 (Oct. 5, 1995) (Ex. 2). The Program Release also emphasizes that only the Secretary has authority to terminate a drug manufacturer's Medicaid participation. *Id.* Likewise, Program Release 71 specifies that CMS, ***not*** the States, is responsible for addressing a manufacturer's failure to fulfill its obligations under the Rebate Agreement. *HCFA/CMS Medicaid Drug Rebate Program Release No. 71* at 4 (Nov. 20, 1997) (Ex. 3).